



FIG. 1

2/40

cancer_protocols_INSTANCE_00039 [instance of Cancer_Clinical_Protocol]	
<b>Label</b>	<b>Version</b>
CALGB 49802	mgk
<b>Title</b>	<b>Authors</b>
Phase III Study of Adriamycin/Taxotere vs Adriamycin/Cytosan for the Adjuvant Treatment of Node Positive or High Risk Node Negative Breast Cancer	M.G. Public
<b>Clinical Algorithm</b>	<b>Reference</b>
CALGB 49802 Level 1	MUSC PRN web page
<b>Context Reference</b>	
<b>Entry Criteria (1 values)</b>	
<b>Protocol Name</b>	<b>Inclusion List</b>
CALGB 49802	<ul style="list-style-type: none"><li>Historically or cytologically confirmed invasive breast cancer</li><li>1-3 histologically involved axillary lymph nodes</li><li>No evidence of metastatic disease (M0)</li><li>Absolute neutrophil count of at least 1,500/mm<sup>3</sup></li><li>Platelet count of at least 100,000/mm<sup>3</sup></li><li>Left ventricular ejection fraction at rest at least 45% by MUGA</li><li>Bilirubin no greater than 1.2 times upper limit of normal (ULN)</li><li>Age 18-70</li><li>Effective contraception required of fertile women</li><li>No prior chemotherapy</li><li>No prior radiotherapy</li><li>No concurrent estrogen therapy</li></ul>
<b>Clinical State Name</b>	
<b>Exclusion List</b>	
<ul style="list-style-type: none"><li>Tumor of any size with direct extension to chest wall or skin (T4)</li><li>Patient is pregnant or nursing</li></ul>	

FIG. 2



**FIG. 3**

4/40

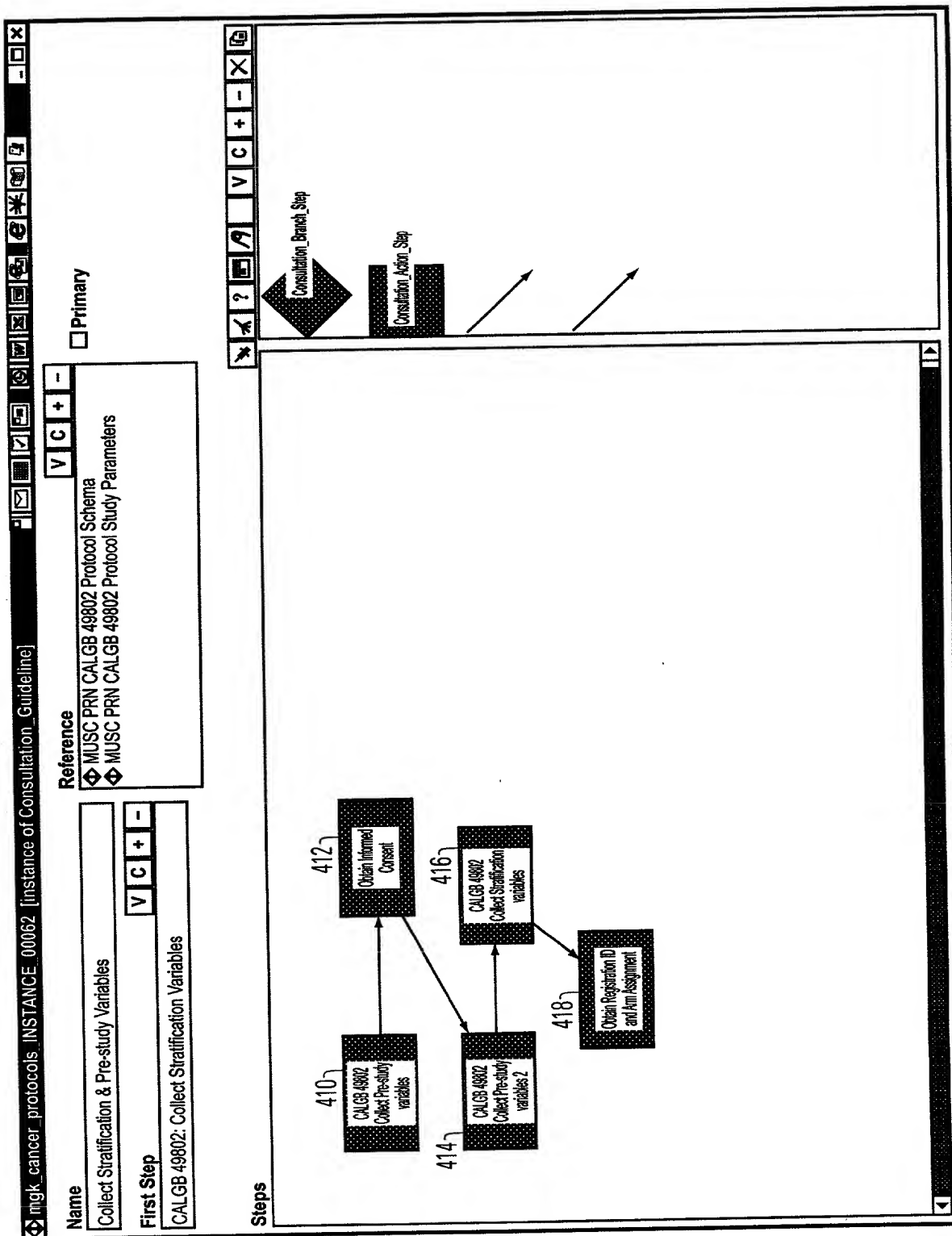


FIG. 4

5/40

mgk\_cancer\_protocols\_INSTANCE\_00063 [instance of Consultation Act...]

<b>Label</b> mgk_cancer_protocols_INSTANCE_00063 [instance of Consultation Act...]	
CALGB 49802: Collect Stratification Variables	
<b>Followed By</b>	<input type="checkbox"/> V <input type="checkbox"/> C <input type="checkbox"/> + <input type="checkbox"/> -
<input type="text"/>	
<b>Rule In</b>	<input type="checkbox"/> V <input type="checkbox"/> C <input type="checkbox"/> + <input type="checkbox"/> -
<input type="text"/>	
<b>Rule Out</b>	<input type="checkbox"/> V <input type="checkbox"/> C <input type="checkbox"/> + <input type="checkbox"/> -
<input type="text"/>	
<b>References</b> <input type="checkbox"/> V <input type="checkbox"/> C <input type="checkbox"/> + <input type="checkbox"/> -	
<input type="text"/>	

- ◆ Evaluate lymph node status
- ◆ Evaluate menopausal status
- ◆ Evaluate estrogen receptor status
- ◆ Evaluate progesterone receptor status

FIG. 5

6/40

2040E0" 28T02660

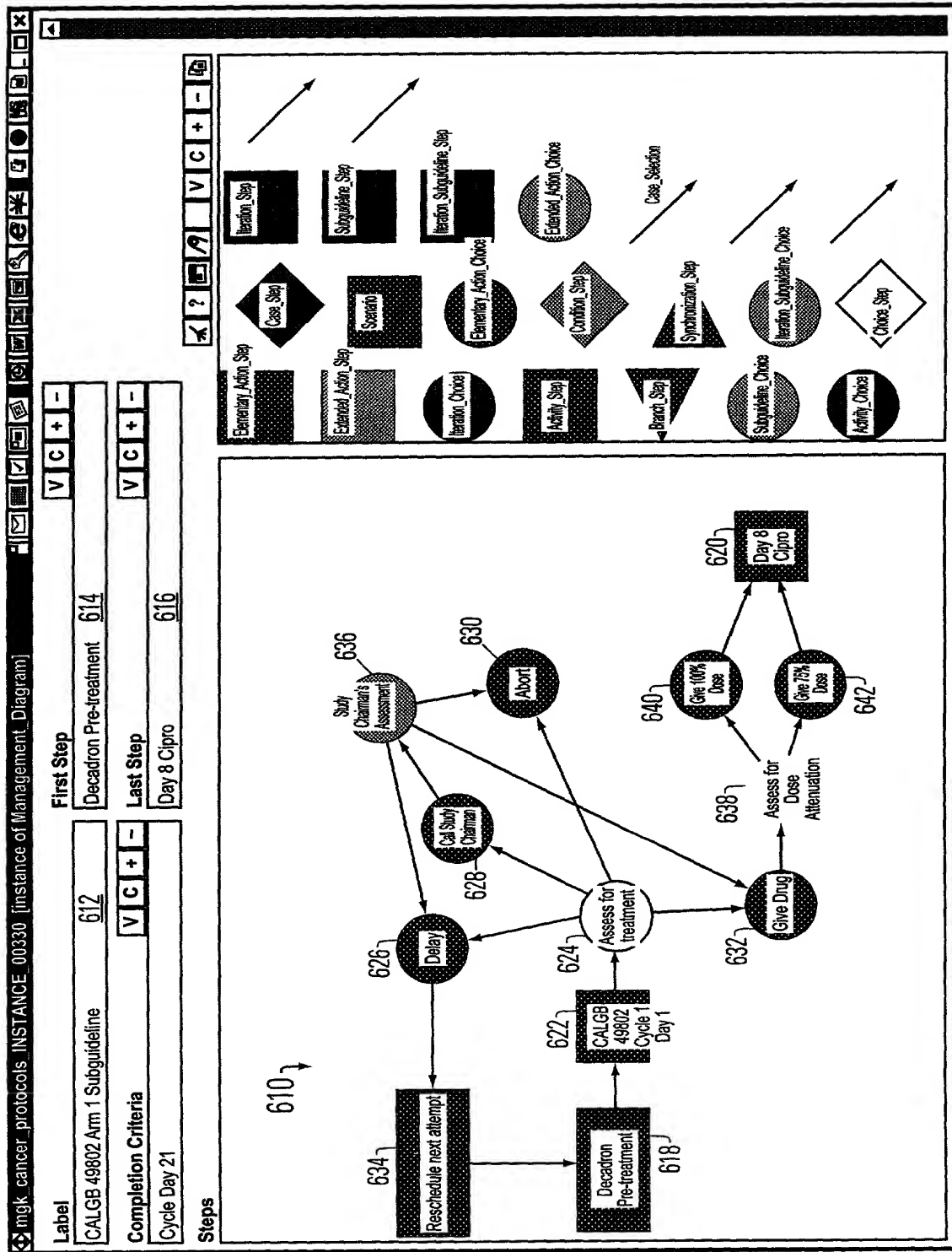


FIG. 6

7/40

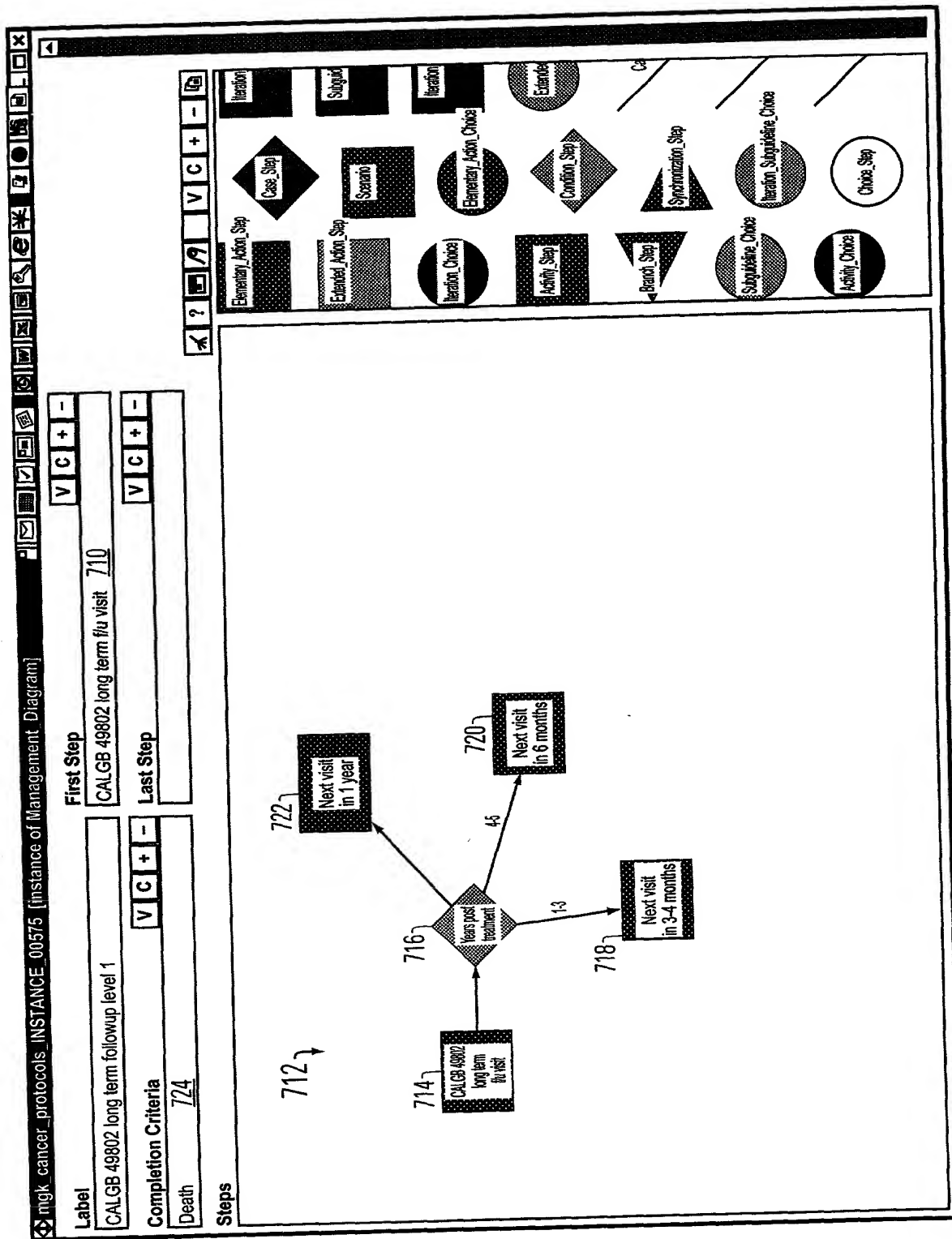


FIG. 7

2040000 28702660

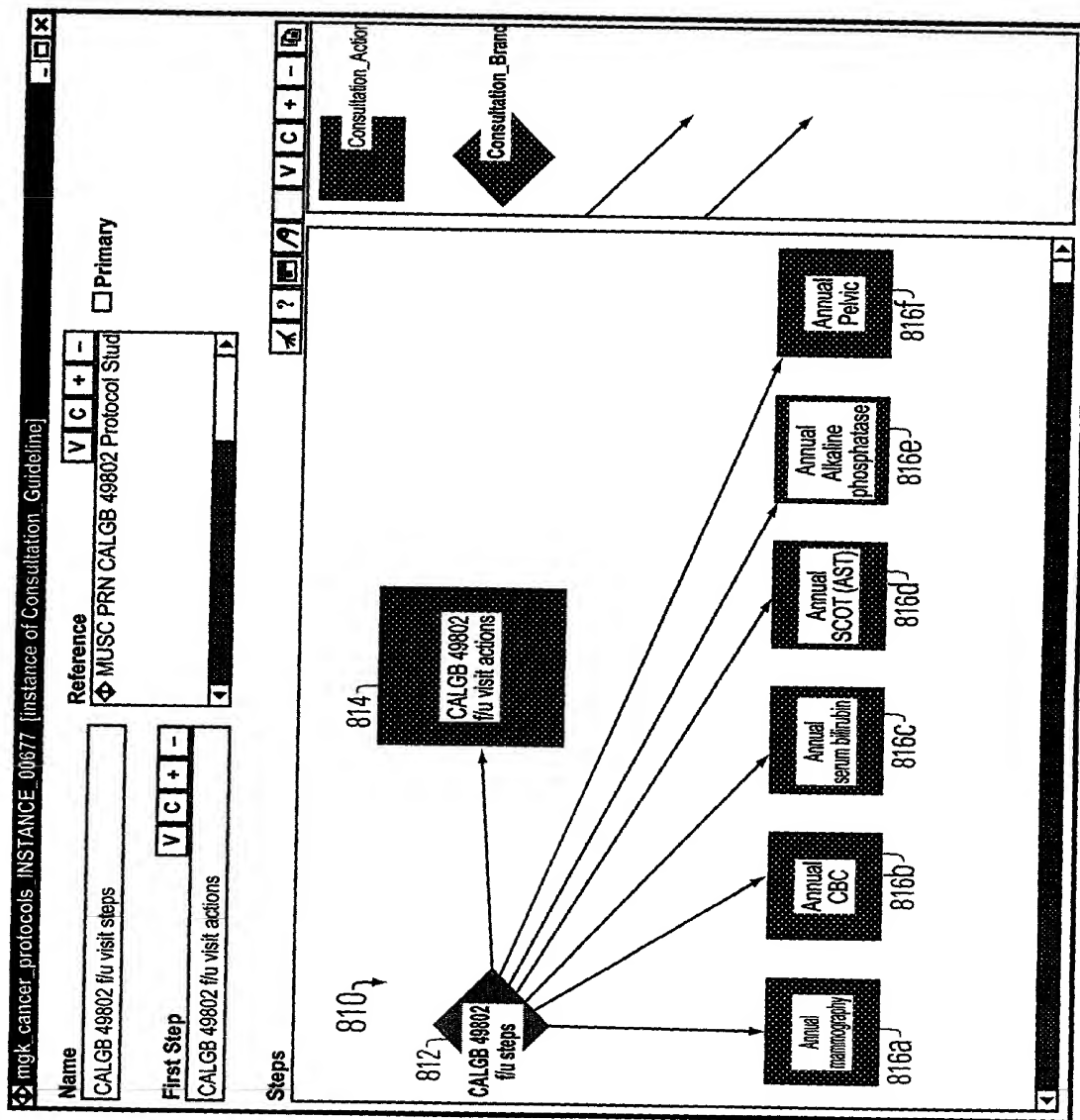


FIG. 8



9/40

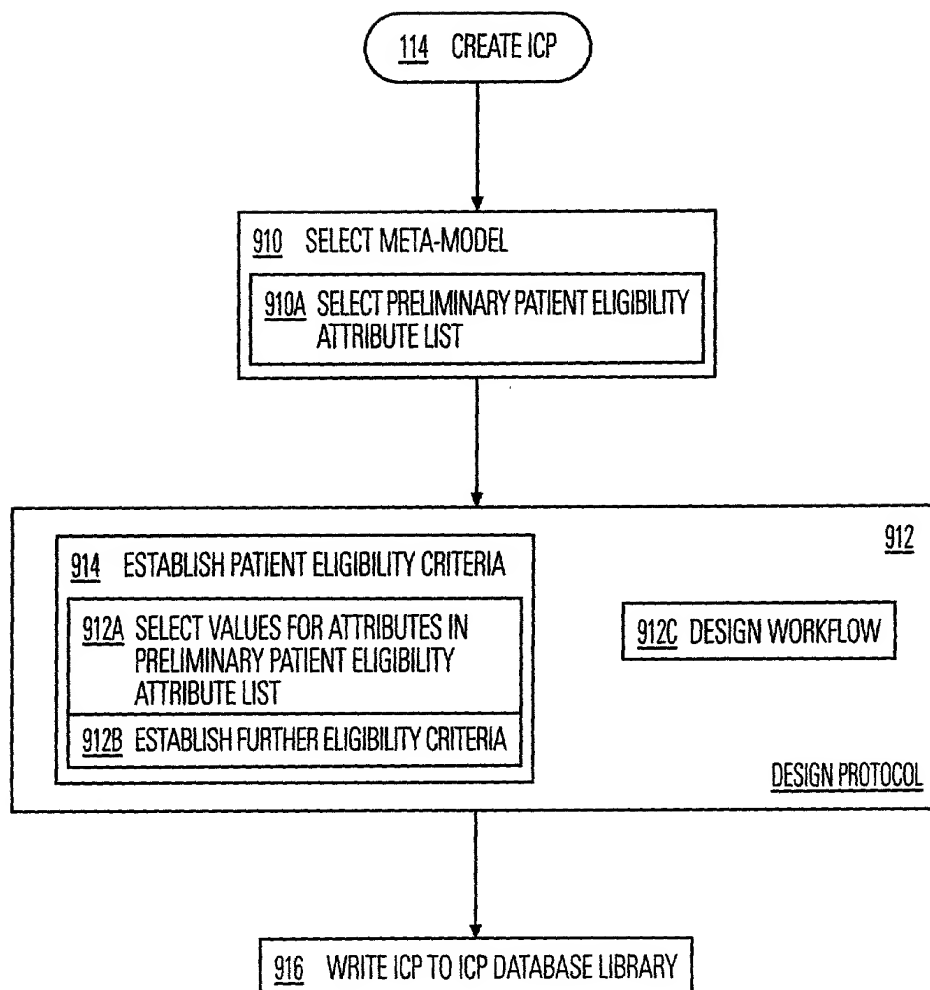


FIG. 9

10/40

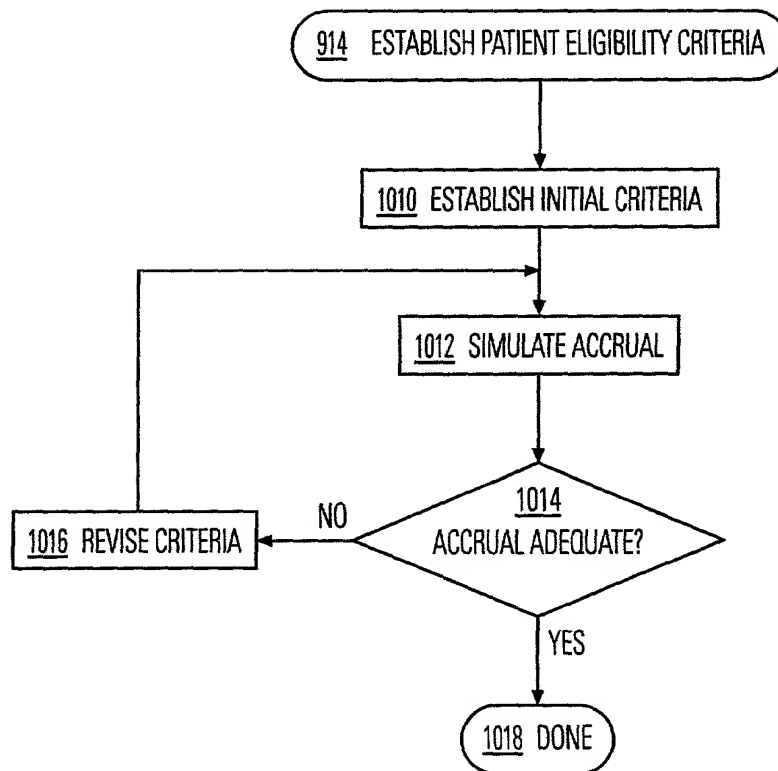


FIG. 10

11/40

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.pprj]

Project Edit Window Help

Classes Subclass V C X

Relationship:   
ProtocolElement<sup>A</sup> 1112  
EligibilityCriteriaSet 1124  
PatientManagementTask 1130  
ProtocolSchemaDiagram<sup>M</sup> 1132  
Visit 1128  
VisitToVisitTransition<sup>M</sup>  
DiseaseArea  
Disease 1150  
DiseaseQualifiers<sup>A</sup> 1110  
ModelVersion

Forms Instances

© Protocol (Instance of rdfs:Class)

Name Protocol Constraints V C + -

Role Concrete

Documentation The document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol also usually gives the background and

Template Slots

Name	Type	Cardinality	Default	Other Facets
protocolSchemaDiagram	Instance	Single		classes={ProtocolSchemaDiagram}
protocolTitle	String	Single		
quickScreenCriterion	Symbol	Single		
rdfs:isDefinedBy	Instance	Single		values={Prostate Cancer, Colorectal Cancer, Breast Cancer}
rdfs:seeAlso	Instance	Single		1122 classes={URI, rdfs:Resource}
resource uri	Instance	Single		classes={URI}
shortDescription	String	Single		
siteAccrualTarget	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		
sponsor	String	Single		
sponsorAccrualTarget	String	Single		
studyChair	String	Single		
trialPhase	String	Single		values={Phase I, Phase II, Phase III, Phase IV, Phase V, Phase VI}
trialStatus	Symbol	Single		values={On Hold, Terminated, Active}

Rdfs:isDefinedBy V C + -

Rdfs:seeAlso V C + -

Resource Uri 1114

FIG. 11

12/40

FastTrack Protocol\_INSTANCE\_00212 [instance of Protocol]

<b>ProtocolTitle</b> A Phase III Study of Paclitaxel via Weekly 1-Hour Infusion v	<b>Version</b> Update #1
<b>ProtocolIdentifier</b> CALGB 9840	<b>VersionDate</b> December 15
<b>OfficialSourceDocument</b> <a href="http://pm.musc.edu/research/protocol/deptmed/divhono/br">http://pm.musc.edu/research/protocol/deptmed/divhono/br</a>	<b>EligibilityCriteriaSet</b> V C + - CALGB 9840 Eligibility Criteria 1212
<b>ShortDescription</b> CALGB 9840	<b>LongDescription</b>
<b>StudyChair</b> Andrew D. Seidman, M.D.	
<b>Sponsor</b> CALGB	
<b>QuickScreenCriterion</b> 1210 Breast Cancer	<b>FirstVisit</b> V C + - Screening Visit
<b>ProtocolObjectives</b> To compare "standard" (S) paclitaxel at 175 mg/m2 via 3-hour infusion every 3 weeks to "dose-dense" (DD) paclitaxel at 80 mg/m2 via 1-hour infusion every week	<b>ProtocolSchemaDiagram</b> V C + - CALGB 9840 Schema 1214
<b>TrialStatus</b> Active	<b>AccrualStatus</b> Open for accrual
<b>TrialPhase</b> Phase III	<b>TrialType</b> Cooperative-group

FIG. 12

13/40

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppr]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

φ THING<sup>A</sup>

- ⊖ SYSTEM-CLASS<sup>A</sup>
- ⊖ Diagram\_Entity
- ⊖ Date
- ⊖ ProtocolElement<sup>A</sup> — 1112
- ⊖ EligibilityCriteriaSet — 1124
- ⊖ EligibilityCriterion
- ⊖ PatientManagementTask — 1130
- ⊖ Protocol — 1116
- ⊖ ProtocolSchemaDiagram<sup>M</sup> — 1132
- ⊖ Visit — 1128
- ⊖ VisitToVisitTransition<sup>M</sup>
- ⊖ DiseaseArea
- ⊖ Arm
- ⊖ WeightedPath
- ⊖ ApplicationArea
- ⊖ VisitCycle
- ⊖ Disease<sup>A</sup>
- ⊖ DiseaseQualifiers<sup>A</sup>
- ⊖ ModelVersion

⊖ EligibilityCriteriaSet (Instance of rdfs:Class)

Name: EligibilityCriteriaSet

Role: Concrete

Constraints: V C + -

Documentation: A criterion which determines whether or not a subject is eligible to participate in the study. A criterion is either an inclusion criterion that prospective subjects must meet to be eligible, or an

Template Slots

Name	Type	Cardinality	Default	Other Facets
exclusionCriteria	Instance	Multiple		classes={EligibilityCriterion}
inclusionCriteria	Instance	Multiple		classes={EligibilityCriterion}
longDescription	String	Single		
rdfs:isDefinedBy	Instance	Single		classes={URI,rdfs:Resource}
rdfs:seeAlso	Instance	Single		classes={URI,rdfs:Resource}
resource uri	Instance	Single		classes={URI}
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Rdfs:isDefinedBy: V C + -

Rdfs:seeAlso: V C + -

Resource Uri: 66 V + -

1310

FIG. 13

14/40

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CAL GB 9840\FastTrack Protocol.ppr]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

① THING<sup>A</sup>  
② SYSTEM-CLASS<sup>A</sup>  
③ Diagram\_Entity  
④ Date  
⑤ ProtocolElement<sup>A</sup> — 1112  
⑥ EligibilityCriteriaSet — 1124  
⑦ EligibilityCriterion  
⑧ PatientManagementTask — 1130  
⑨ Protocol — 1116  
⑩ ProtocolSchemaDiagram<sup>M</sup> — 1132  
⑪ Visit — 1128  
⑫ VisitToVisitTransition<sup>M</sup>  
⑬ DiseaseArea  
⑭ WeightedPath  
⑮ ApplicationArea  
⑯ VisitCycle  
⑰ Disease<sup>A</sup>  
⑱ DiseaseQualifiers<sup>A</sup>  
⑲ ModelVersion

⑥ EligibilityCriterion (Instance of rdfs:Class)

Name: EligibilityCriterion

Role: Concrete

Constraints: V C + -

Documentation: A criterion which determines whether or not a subject is eligible to participate in the study. A criterion is either an inclusion criterion that prospective subjects must meet to be eligible, or an

Template Slots

Name	Type	Cardinality	Default	Other Facets
longDescription	String	Single		
rdfs:isDefinedBy	Instance	Single		classes={URL,rdfs:Resource}
rdfs:seeAlso	Instance	Single		classes={URL,rdfs:Resource}
resource uri	Instance	Single		classes={URI}
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Rdfs:isDefinedBy: V C + -

Rdfs:seeAlso: V C + -

Resource Uri: 66 ± V + -

1410

FIG. 14

15/40

FastTrack Protocol\_INSTANCE\_00074 [instance of EligibilityCriteriaSet]

ShortDescription

CALGB 9840 Eligibility Criteria

InclusionCriteria

V C + -

Female

Breast adenocarcinoma that is inoperable, recurrent, or metastatic

More than 4 weeks since last chemotherapy

More than 6 weeks since treatment with nitrosureas, melphalan, o

More than 4 weeks since last hormonal therapy OR tumor measur

Age >= 18

Measurable disease

Granulocytes >= 1,500 / ul

Platelet count >= 100,000 / ul

Creatinine <= 2.0 mg/dl

Bilirubin within institutional normal limits

SGOT (AST) <= 3X upper limits of normal

Greater than 2 weeks from prior surgery

ExclusionCriteria

V C + -

More than 1 prior chemotherapy regimens for metastatic or locally

CNS metastases if untreated or symptomatic—1510

Prior taxane for metastatic or locally-advanced breast cancer

Prior taxane in adjuvant setting where patient remained disease fr

Leptomeningeal carcinoma

LongDescription

SiteLongDescription

SiteShortDescription

Rdfs:isDefinedBy

V C + -

Rdfs:seeAlso

V C + -

Resource Uri

66 2 V + -

FIG. 15

16/40

FastTrack Protocol INSTANCE\_00073 [instance of EligibilityCriterion]

<b>ShortDescription</b>
CNS metastases if untreated or symptomatic
<b>LongDescription</b>
Patients with central nervous system metastases are eligible only if the patient has completed cranial irradiation at least 6 months prior, is currently asymptomatic, and is not currently receiving corticosteroids for this condition.
<b>SiteLongDescription</b>
<b>SiteShortDescription</b>

FIG. 16



17/40

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppr]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

Thing<sup>A</sup>  
SYSTEM-CLASS<sup>A</sup>  
Diagram\_Entity  
Date  
ProtocolElement<sup>A</sup> — 1112  
EligibilityCriteriaSet — 1124  
EligibilityCriterion  
PatientManagementTask — 1130  
Protocol — 1116  
ProtocolSchemaDiagram<sup>M</sup> — 1132  
Visit — 1128  
VisitToVisitTransition<sup>M</sup>  
DiseaseArea  
App<sup>M</sup>  
WeightedPath  
ApplicationArea  
VisitCycle  
Disease<sup>A</sup>  
DiseaseQualifiers<sup>A</sup>  
ModelVersion

1128

1110

Visit (Instance of rdfs:Class)

Name  
Visit

Constraints V C + -

Documentation  
An actual encounter between the provider and a patient on study. A number of possible visits are associated with a study (Protocol).

Role  
Concrete

Template Slots

Name	Type	Cardinality	Default	Other Facets
dataManagementTasks — 1716	Instance	Multiple		classes={ManagementTask}
longDescription	String	Single		
patientManagementTasks	Instance	Multiple		classes={VisitToVisitTransition}
possibleVisitTransitions — 1714	Instance	Multiple		classes={URI, rdfs:Resource}
rdfs:isDefinedBy	Instance	Single		classes={URI, rdfs:Resource}
rdfs:seeAlso	Instance	Single		classes={URI}
resource uri	Instance	Single		
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Rdfs:isDefinedBy V C + -

Rdfs:seeAlso V C + -

Resource Uri 64 V + -

1710

Superclasses  
ProtocolElement<sup>A</sup>

FIG. 17

18/40

FastTrack Protocol INSTANCE 00014 [Instance of Visit]

ShortDescription

Arm A Treatment Visit

PossibleVisitTransitions

Arm A Treatment to Arm A Treatment Retry #1

Arm A Treatment to Long Term Followup

Arm A Treatment Visit to Arm A Treatment Visit

DataManagementTasks

Submit Form C-116

Submit Form C-118

Submit Form C-080

Submit Form C-344 + Form C-080 (\*)

Submit Form C-344 + Form C-272 (\*)

Submit Form C-113 (\*)

Submit Form C-260 (\*)

Submit Form C-300 (\*)

PatientManagementTasks

Confirm granulocytes  $\geq 1500 / \mu l$

Confirm no G-CSF given in past 24 hours

Give Dexmethosone 10 mg IV, 30 minutes

Give Diphenhydramine 50 mg IV, 30 minutes

Give Cimetidine 300 mg IV, 30 minutes

Give anti-emetics (\*)

Give Arm A Paclitaxel treatment

Give G-CSF (\*)

Evaluate Patient Response

Schedule next visit

LongDescription

Arm A of the CALG 9840 consists of treatment with Paclitaxel 175 mg/m<sup>2</sup> administered as a 3 hour infusion intravenously every three weeks. One cycle is equivalent to one infusion. Treatment cycles will be repeated every 21 days as long as the patient has stable or responding disease. Granulocyte count must be  $\geq 1500 / \mu l$  and platelet count must be  $\geq 100,000 / \mu l$  on day 1 of each cycle. Patients should receive a minimum of two cycles of therapy, unless there is rapid disease progression ( $>50\%$  increase in product of bi-dimensional measurements).

SiteLongDescription

SiteShortDescription

FIG. 18

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.pprj]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

THING<sup>A</sup>

SYSTEM-CLASS<sup>A</sup>

Diagram\_Entity

Date

ProtocolElement<sup>A</sup> - 1112

EligibilityCriteriaSet - 1124

EligibilityCriterion

PatientManagementTask - 1130

Protocol - 1116

ProtocolSchemaDiagram<sup>M</sup> - 1132

Visit - 1128

VisitToVisitTransition<sup>M</sup>

DiseaseArea

App

WeightedPath

ApplicationArea

VisitCycle

Disease<sup>A</sup>

DiseaseQualifiers<sup>A</sup>

ModelVersion

ManagementTask (Instance of rdfs:Class)

Name

ManagementTask

Constraints

V C + -

Documentation

A task related to this visit. Includes:  
checks that tasks prior to this visit  
occurred, oks that tasks performed  
during this visit were done, or  
reminders for tasks to perform before

Role

Concrete

Template Slots

Name	Type	Cardinality	Default	Other Facets
longDescription	Symbol	Single		values={Medium,High,Low}
longDescription	String	Single		
rdfs:isDefinedBy	Instance	Single		classes={URI,rdfs:Resource}
rdfs:seeAlso	Instance	Single		classes={URI,rdfs:Resource}
resource uri	Instance	Single		classes={URI}
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Rdfs:isDefinedBy

V C + -

Rdfs:seeAlso

V C + -

Resource Uri

64 1 1 V + -

Superclasses

+ -

ProtocolElement<sup>A</sup>

1910

FIG. 19

20/40

FastTrack Protocol\_INSTANCE\_00206 [Instance of ManagementTask]

ShortDescription

Give Arm A Paclitaxel treatment

LongDescription

Give Paclitaxel 175 mg/m<sup>2</sup> IV, 3hours. This treatment is given to patients in Arm A of the CALGB 9840 protocol. It is given once every 3 weeks. One cycle is equivalent to one infusion. Granulocyte count must be  $\geq 1500/\mu\text{l}$  and platelet count must be  $\geq 100,000/\mu\text{l}$  on day 1 of each cycle in order to proceed with the Paclitaxel infusion. Patients must receive the pre-medication prior to Paclitaxel infusion. If either the granulocyte or platelet count are not adequate, do not continue with treatment. Patients should receive a minimum of 2 cycles unless there is rapid disease progression.

Expected toxicities:

Dose Modifications:

SiteLongDescription

FIG. 20

21/40

FastTrack Protocol\_INSTANCE\_00196 [instance of ManagementTask]

**ShortDescription**  
Submit Form C-116

**LongDescription**  
Submit CALGB Advanced Breast Cancer Followup-form (C-116) every two cycles while on protocol therapy, at 6 & 12 months after end of treatment, at disease progression or initiation of non-protocol therapy.

**SiteLongDescription**

**SiteShortDescription**

FIG. 21

22/40

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppr]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

G:THING<sup>A</sup>  
 G:SYSTEM-CLASS<sup>A</sup>  
 Diagram\_Entity  
 G:Date  
 G:ProtocolElement<sup>A</sup> - 1112  
 G:EligibilityCriteriaSet - 1124  
 G:EligibilityCriterion  
 G:PatientManagementTask - 1130  
 G:Protocol - 1116  
 G:ProtocolSchemaDiagram<sup>M</sup> - 1132  
 G:Visit - 1128  
 G:VisitToVisitTransition<sup>M</sup> - 2210  
 G:DiseaseArea  
 G:Arm  
 G:WeightedPath  
 G:ApplicationArea  
 G:VisitCycle  
 G:Disease<sup>A</sup>  
 G:DiseaseQualifiers<sup>A</sup>  
 G:ModelVersion

Name: VisitToVisitTransition  
 Role: Concrete  
 Constraints: V C + -  
 Documentation: A one-way link between a source visit (first\_object) and a target visit (second\_object). The inherited descriptions specify guidance about when/how/why to make this transition. V C + -

Template Slots	Name	Type	Cardinality	Default	Other Facets
1	first_object - 2214	Instance	Single		classes={Visit}
2	longDescription	String	Single		
3	maximumRelativeTime - 2218	String	Single		
4	minimumRelativeTime - 2220	String	Single		
5	preferredRelativeTime - 2222	String	Single		
6	rdfs:isDefinedBy	Instance	Single		classes={URI,rdfs:Resource}
7	rdfs:seeAlso	Instance	Single		classes={URI,rdfs:Resource}
8	resource uri	Instance	Single		classes={URI}
9	second_object - 2216	Instance	Single		classes={Visit}
10	shortDescription	String	Single		
11	siteLongDescription	String	Single		
12	siteShortDescription	String	Single		

First Object Slot Pointer: V C + -  
 Rdfs:isDefinedBy: V C + -  
 Rdfs:seeAlso: V C + -  
 Second Object Slot Pointer: V C + -

2212

FIG. 22

23/40

1818

FastTrack Protocol\_INSTANCE\_00023 [instance of VisitToVisit Transition]

<b>ShortDescription</b>		<b>PreferredRelativeTime</b>
Arm A Treatment to Arm A Treatment Retry #		7
<b>First Object</b>	V C + -	<b>MaximumRelativeTime</b>
Arm A Treatment Visit		7
<b>Second Object</b>	V C + -	<b>MinimumRelativeTime</b>
Arm A Treatment Retry #1		7

**LongDescription**

If either granulocyte or platelet count are not adequate, blood counts should be repeated weekly and treatment should be instituted when there has been hematologic recovery. Patients receiving G-CSF are not eligible for re-treatment unless they have been off G-CSF for a minimum of 24 hours.

**SiteLongDescription**

☒ IsPreferredTransition 2310

**SiteShortDescription**

FIG. 23

24/40

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppt]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass V C X

φ:THING<sup>A</sup>

- φ:SYSTEM-CLASS<sup>A</sup>
- φ:Diagram\_Entity
- φ:Date
- φ:ProtocolElement<sup>A</sup> - 1112
  - φ:EligibilityCriteriaSet - 1124
  - φ:EligibilityCriterion
  - φ:PatientManagementTask - 1130
  - φ:Protocol - 1116
    - φ:ProtocolSchemaDiagram - 1132
      - φ:Visit - 1128
        - φ:VisitToVisitTransition<sup>M</sup> - 2210
          - φ:DiseaseArea
            - φ:Arm
              - φ:WeightedPath
              - φ:ApplicationArea
              - φ:VisitCycle
              - φ:Disease<sup>A</sup>
              - φ:DiseaseQualifiers<sup>A</sup>
              - φ:ModelVersion

1110

© ProtocolSchemaDiagram (Instance of Network\_Metaclass)

Name: ProtocolSchemaDiagram

Role: Concrete

Constraints: V C + -

Documentation: The ProtocolSchemaDiagram is the part of the protocol which details the design of the trial. A protocol schema's first visit is always at least one screening visit, which is assumed

Template Slots

Name	Type	Cardinality	Default	Other Facets
connectors	Instance	Multiple		classes={VisitToVisitTransition}
diagramNodes	Instance	Multiple		classes={Visit}
last_divider_location	Integer	Single		
layout_information	Instance	Multiple		classes={ObjectLocation}
longDescription	String	Single		
main_panel_height	Integer	Single		
main_panel_width	Integer	Single		
rdfs:isDefinedBy	Instance	Single		classes={URI,rdfs:Resource}
resource uri	Instance	Single		classes={URI,rdfs:Resource}
shortDescription	String	Single		classes={URI}
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Node Slot: diagramNodes V C + -

Rdfs:isDefinedBy V C + -

Rdfs:seeAlso V C + -

Superclasses: ProtocolElement<sup>A</sup> + -

FIG. 24



25/40

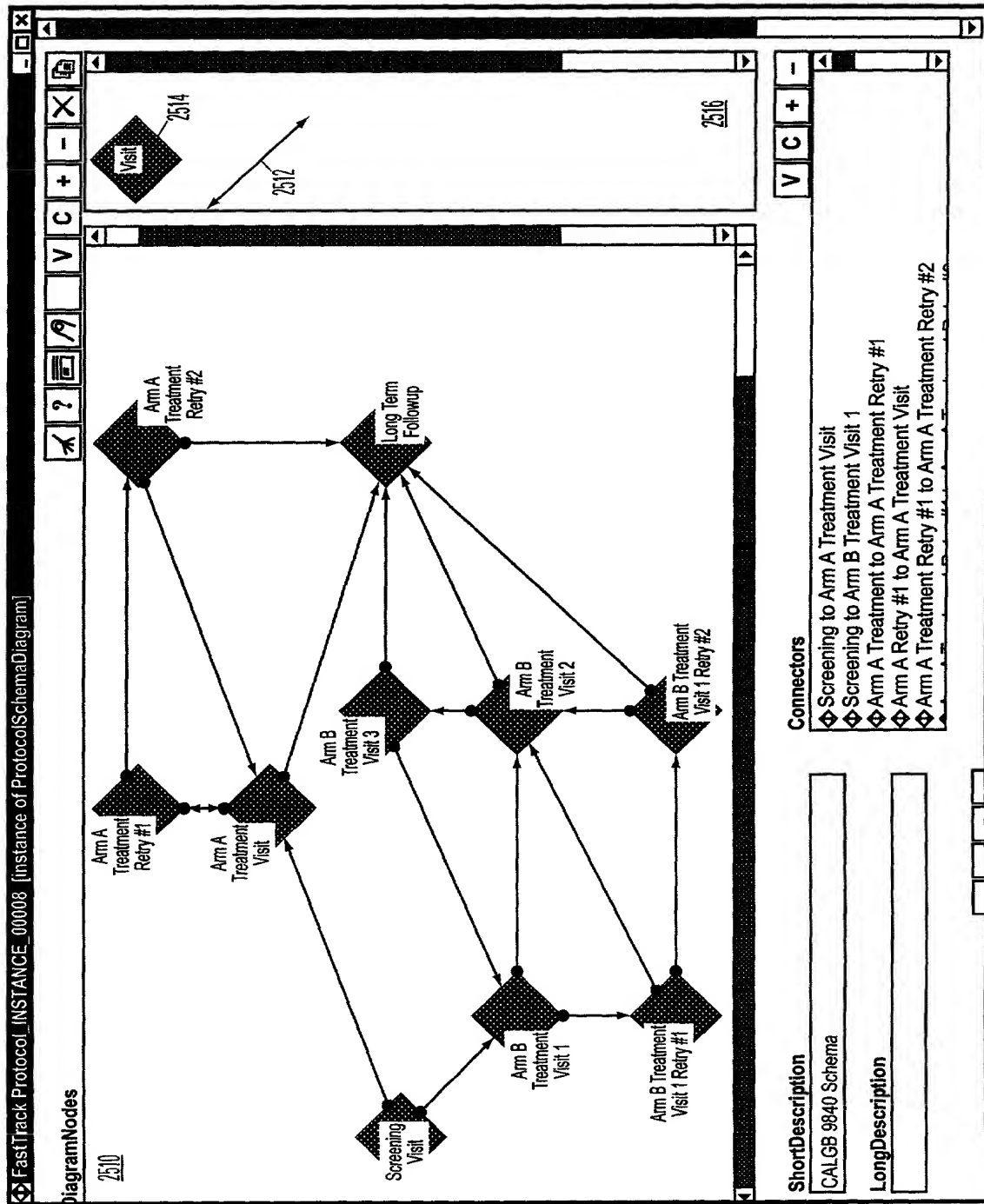


FIG. 25

26/40

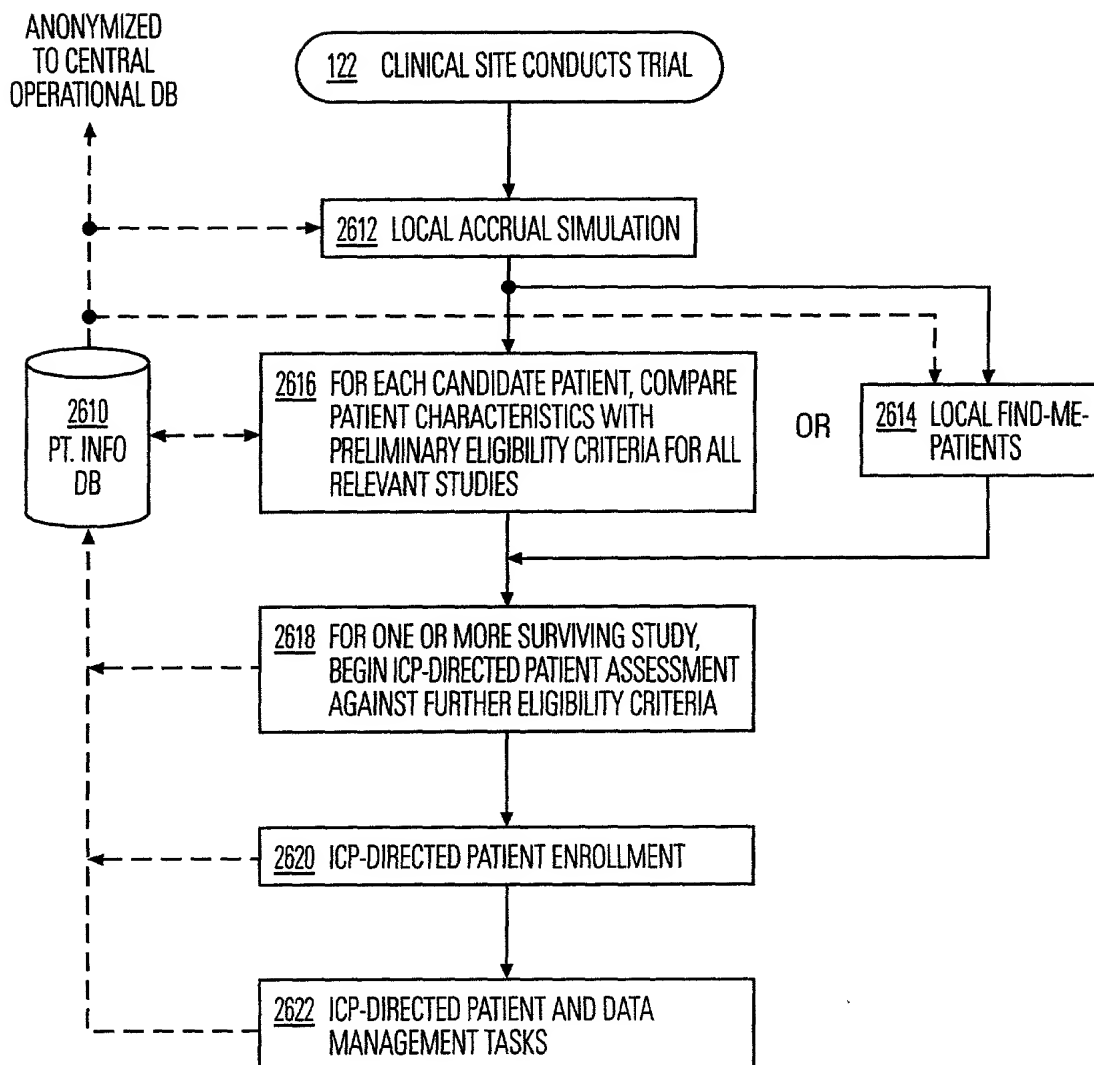


FIG. 26

27/40

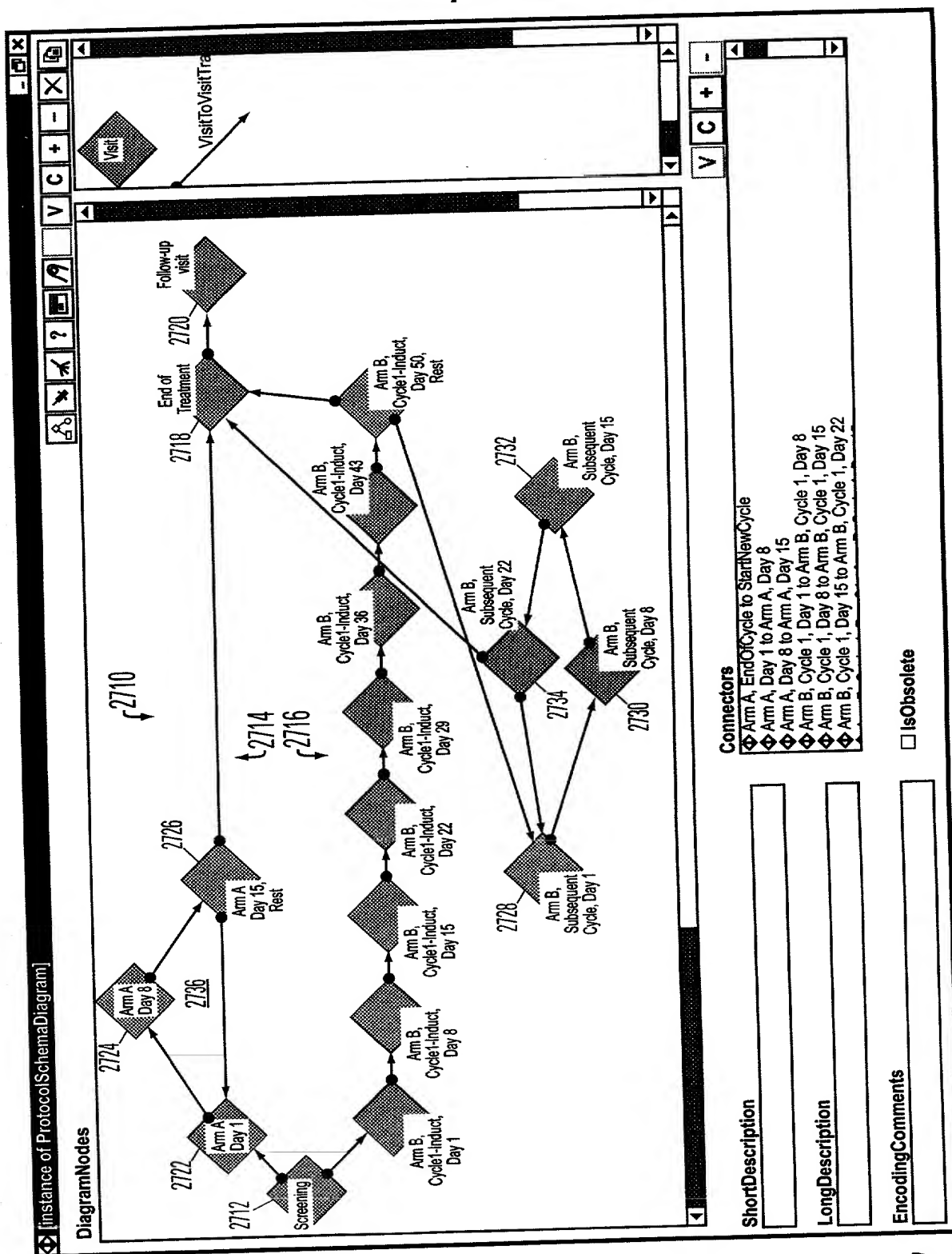


FIG. 27

28/40

Protocol Protégé-2000 [D:\Work\Sample\Protocol.pprj]  
Project Edit Window Help

Classes Slots Forms Instances  
Relationship: Subclass V C A X

Arm (Instance of :STANDARD-CLASS)

Name: Arm Constraints: V C + Documentation:

Role: Concrete

Template Slots

Name	Type	Cardinality	Default	Other Facets
drillDown	Boolean	single	false	
encodingComments	String	single		
isObsolete	Boolean	single	false	
longDescription	String	single		
obsoleteVisits	Instance	multiple		classes={Visit, VisitCycle}
shortDescription	String	single		
Visits	Instance	multiple		classes={Visit, VisitCycle}

1110

Superclasses: ProtocolElement<sup>A</sup>

2810

FIG. 28

29/40

09970182-030402-28102660

[instance of Arm]

ShortDescription

Arm A --2710

LongDescription

Arm A: Gemcitabine and Irinotecan HCl (CPT-11)

EncodingComments

Editorial change

Visits

V C + -

◆ Screening --2712

◆ Arm A, Day 1 --2722

◆ Arm A, Day 8 --2724

◆ Arm A, Day 15, Rest --2726

◆ End of Treatment --2718

◆ Follow-up Visit --2720

ObsoleteVisits

V C + -

☐ IsObsolete

☐ DrillDown

FIG. 29

30/40

Protocol Protégé-2000 [D:\Work\Sample\Protocol.ppt]

Project Edit Window Help

Classes Slots Forms Instances

Relationship: Subclass V C X

φ C:THINGA

- φ C:SYSTEM-CLASSA
- φ C:Diagram\_Entity
- φ C:Date
- φ C:ProtocolElementA
- φ C:EligibilityCriteriaSet
- φ C:EligibilityCriterion
- φ C:PatientManagementTask
- φ C:Protocol
- φ C:ProtocolSchemaDiagramM
- φ C:Visit
- φ C:VisitToVisitTransitionM
- φ C:DiseaseArea
- φ C:Arm — 1150
- φ C:WeightedPath — 1152
- φ C:ApplicationArea
- φ C:VisitCycle — 1154
- φ C:DiseaseA
- φ C:DiseaseQualifiersA
- φ C:ModelVersion

WeightedPath (Instance of :STANDARD-CLASS)

Name: WeightedPath

Constraints: V C + -

Documentation:

Role: Concrete

Template Slots

Name	Type	Cardinality	Default	Other Facets
drillDown	Boolean	single	false	
encodingComments	String	single		
isObsolete	Boolean	single	false	
longDescription	String	single		
obsoleteVisits	Instance	multiple		classes={Visit, VisitCycle}
pathWeight — 3014	Integer	single	1	
shortDescription	String	single		
Visits — 3012	Instance	multiple		classes={Visit, VisitCycle}

3010

Superclasses

C Arm

FIG. 30

31/40

3110

[instance of WeightedPath]

<b>ShortDescription</b> Arm A Path	<b>Visits</b> V C + - ◆ Screening → 2712 ◆ Arm A Cycle → 2736 ◆ End of Treatment → 2718 ◆ Follow-up cycle → 2720
<b>LongDescription</b> 	
<b>EncodingComments</b> 	<b>PathWeight</b> 1
<input type="checkbox"/> IsObsolete <input type="checkbox"/> DrillDown	

FIG. 31





33/40

2736

The screenshot shows a software window titled "[instance of VisitCycle]". It contains several input fields and controls:

- ShortDescription:** A text box containing "Arm A Cycle".
- LongDescription:** An empty text box.
- EncodingComments:** An empty text box.
- VisitsInCycle:** A list box with three items: "Arm A, Day 1 --2722", "Arm A, Day 8 --2724", and "Arm A, Day 15, Rest --2726". Above this list are buttons labeled "V", "C", "+", and "-".
- CycleCount:** A text box containing the number "3".
- DrillDown:** An unchecked checkbox.
- IsObsolete:** An unchecked checkbox.

FIG. 33

34/40

### Timeline Simulation Process Flow

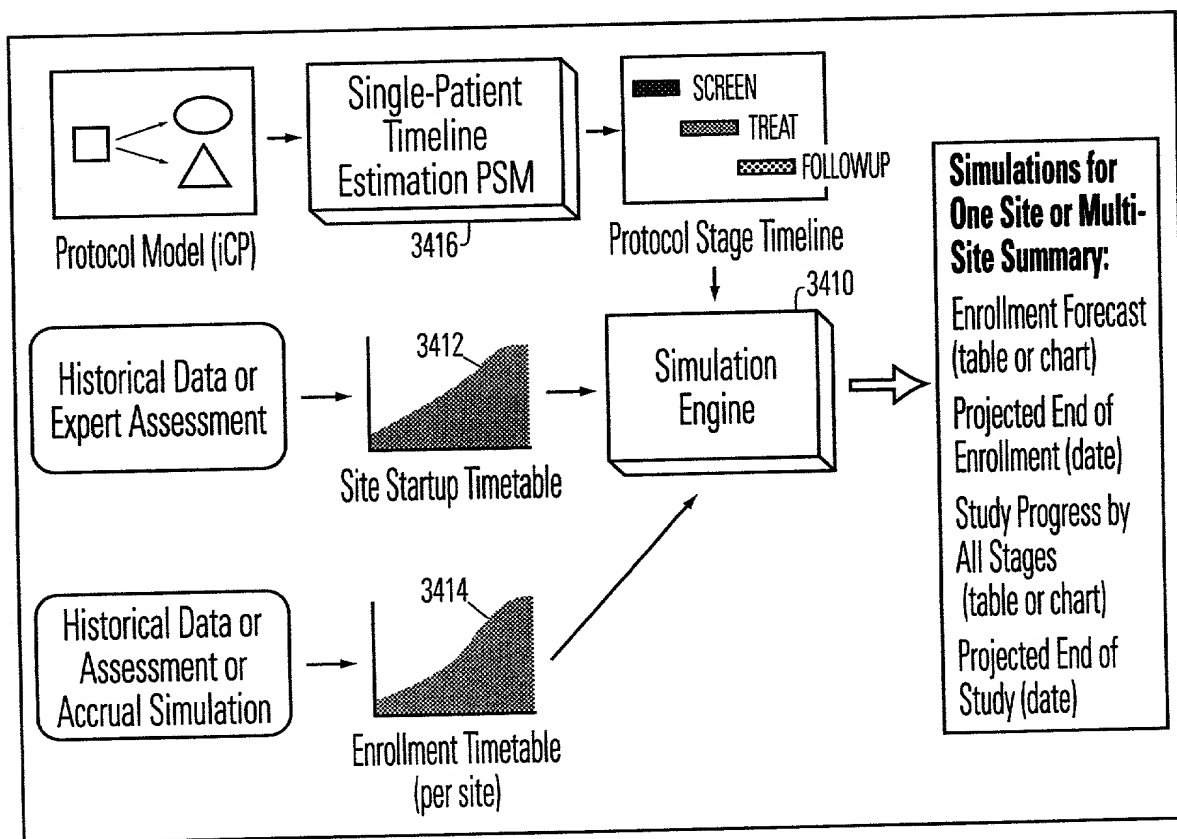


FIG. 34

35/40

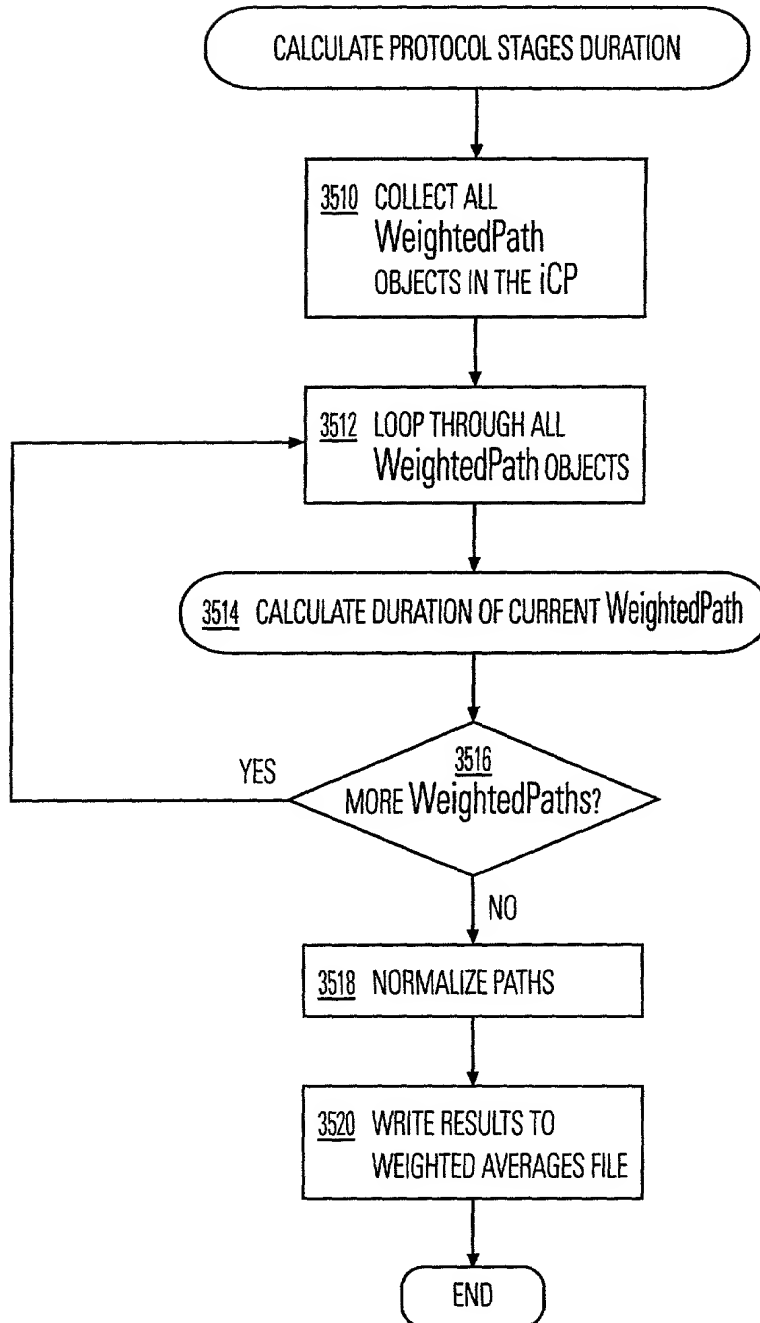


FIG. 35

36/40

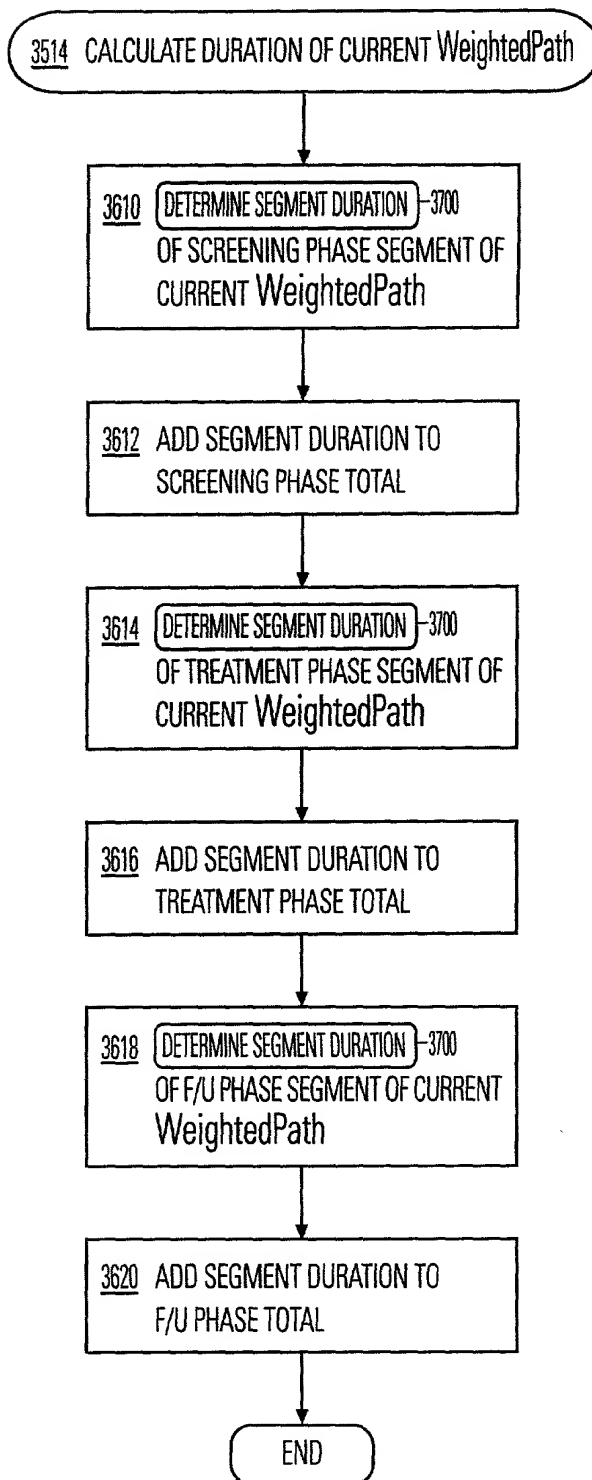


FIG. 36

37/40

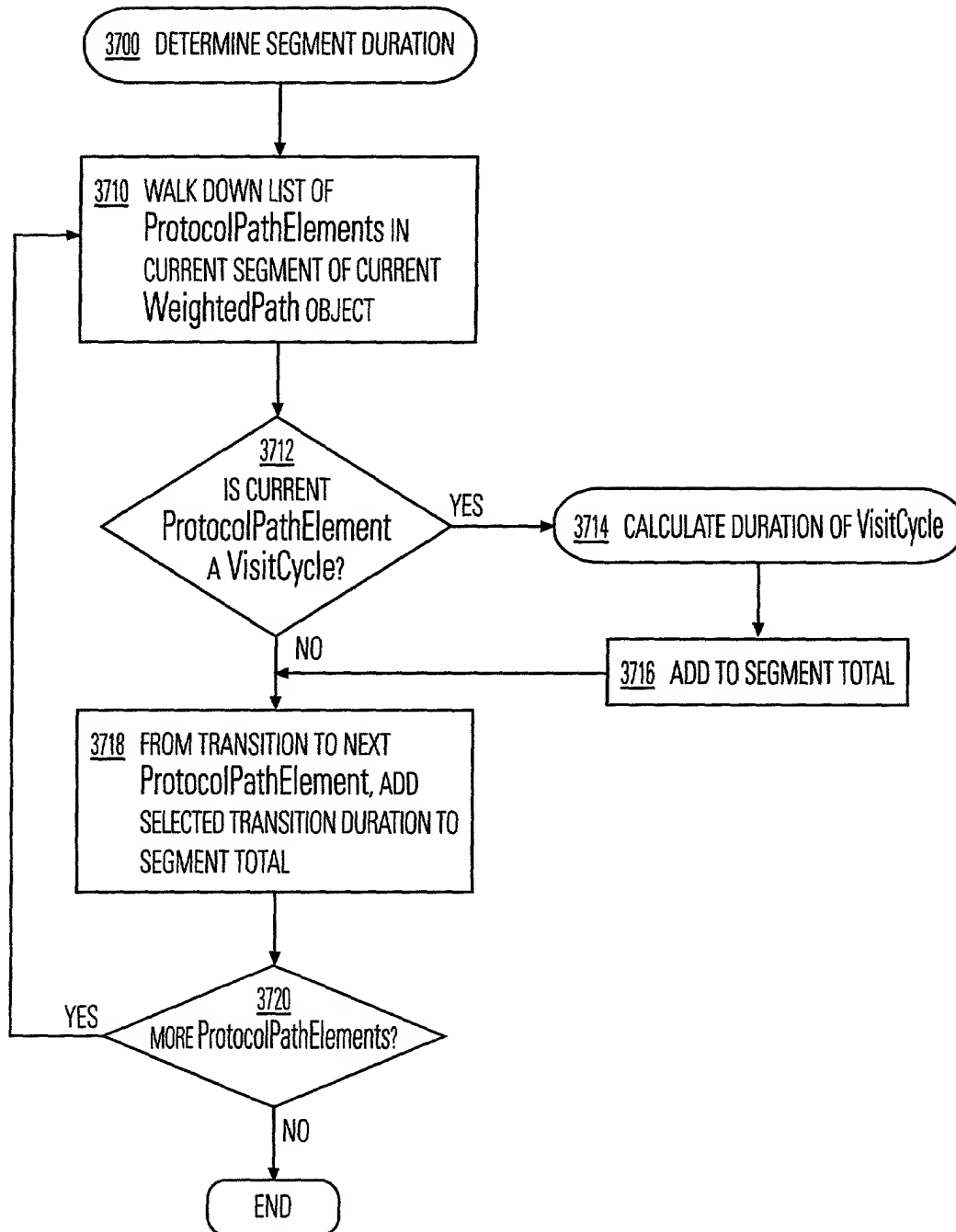


FIG. 37

38/40

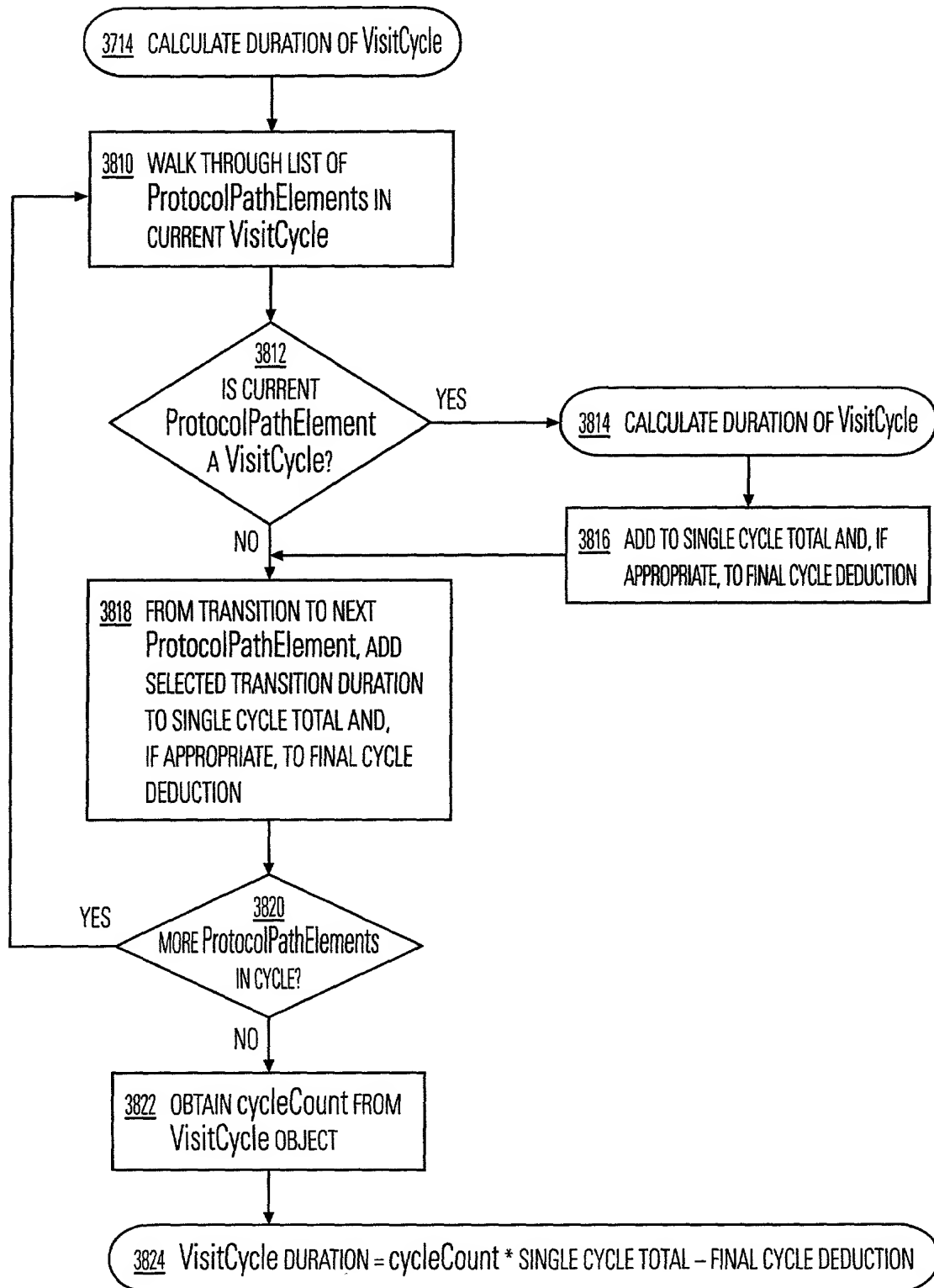
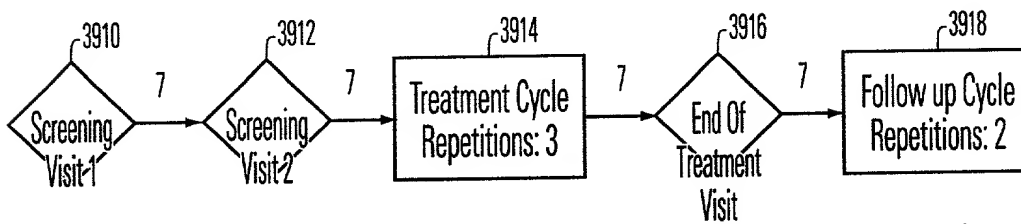


FIG. 38

39/40

Screening duration =  $7 + 7 = 14$   
 Treatment =  $3 * (1 + 1 + 1) - 1 + 7 + 7 = 22$   
 Follow up = 30



ProtocolPathElements:  
 Visits: diamonds  
 VisitCycles: rectangles

Expansion of VisitCycles

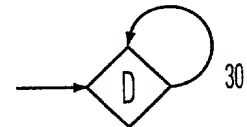
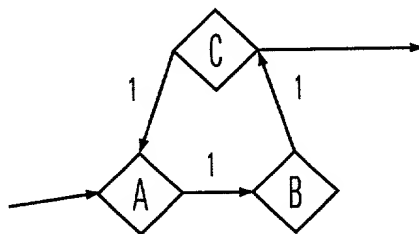
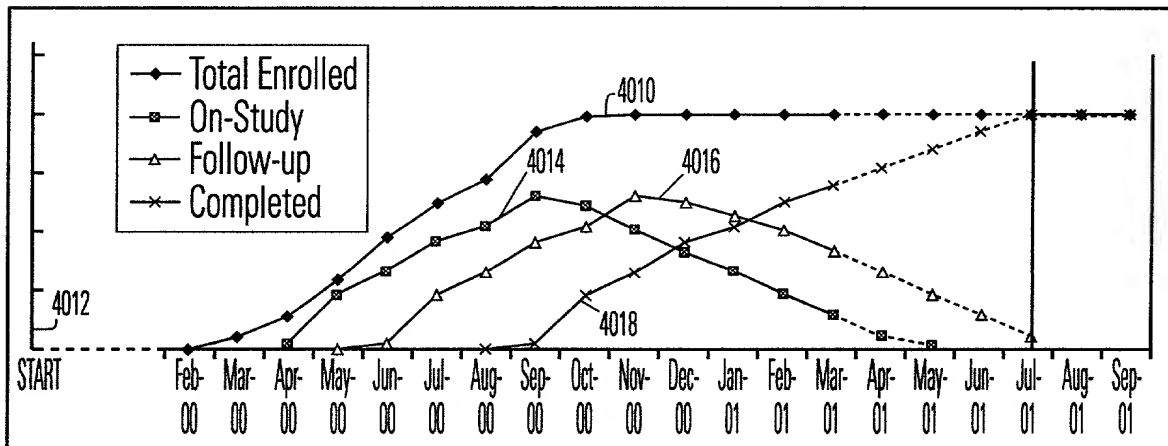


FIG. 39

40/40

### Forecast Trial Completion



*The last patient should complete follow-up in July 2001*

**FIG. 40**